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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,501	06/26/2003	Janice A. Jordan	2422 US	6284

26356 7590 09/27/2004

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EXAMINER

FAY, ZOHREH A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/606,501

Applicant(s)

JERDAN ET AL.

Examiner

Zohreh Fay

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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Claims 1-18 are presented for examination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Penn et al. and Yaacobi (6,413,540).

Penn et al. Teach the use of the claimed compound, anecortave acetate in a pharmaceutical formulation for the inhibition of angiogenesis of ocular conditions such as macular degeneration. See the entire abstract. The intravitreal injection is also taught by the above reference. Yaacobi teaches the use of a device, which can be implanted into the eye for the drug delivery purposes. The use of the claimed compound anecortave acetate is taught by the above reference. See claim 11. The treatment of macular degeneration is one of the conditions which the claimed device is used for. See column 2, lines 54-67. The above references differ from the claimed invention in the prevention of loss of vision associated with AMD, maintaining visual acuity associated with AMD, the inhibition of lesion growth and the inhibition of blood vessel growth associated with AMD. It would have been obvious to a person skilled in the art to use the claimed compound for the prevention and inhibition of disorders associated with AMD, considering that the relied upon references teach the use of such agent for the treatment of macular degeneration.

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One skilled in the art would have been motivated to employ the teachings of the above references, since they relate to the use of the claimed compound, anecortave acetate for the treatment of AMD. to use of a compound being effective for the treatment of AMD and use it for the prevention or inhibition of symptoms associated with AMD is considered to be within the skill of artisan in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-18 are properly rejected under 35 U.S.C. 103.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibition or maintaining visual acuity, does not reasonably provide enablement for prevention of loss of visual loss. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are:

1) The nature of the invention:

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The claims are drawn to a method of prevention of loss of visual acuity associated with AMD, using anecortave acetate.

2) The state of the prior art:

The prior art does not recognize that the prevention of loss of acuity associated with AMD is accomplished easily. According to LANCE, Current Medical Diagnosis and treatment, the photodynamic laser therapy in treating AMD limits the visual field loss, but repeated treatment is necessary and the cost is high. The above source also indicates that there is no specific treatment for atopic age related macular degeneration, but as with the exudative form patients often benefit from visual aids.

3) The relative skill of those in the art:

The relative skill of those in the art is high.

4) The predictability and unpredictability of the art:

The unpredictability of the pharmaceutical and chemical art is high.

5) The breadth of the claims:

The claims are drawn to the prevention of visual acuity associated with. Such claims are not considered to be broad in nature.

6) The amount of direction or guidance presented:

Applicant's specification provides guidance and it is only enabled for the treatment of AMD or the reduction in visual field loss. However the specification provides no guidance, to enable one skilled in the art to prevent visual field loss associated with AMD.

7) The presence or absence of working examples:

The examples in applicant's specification are drawn to the treatment of AMD and the reduction of visual acuity associated with AMD. However, there are no examples to demonstrate the "prevention" of visual acuity associated with AMD.

8) The quantity of experimentation necessary:

Since the examples in the specification are drawn to the treatment of AMD or the reduction of loss of visual acuity associated with AMD, one of ordinary skill in the art would be burdened with undue experimentation to determine the effectiveness of the claim compound in preventing loss of visual acuity associated with AMD.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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